UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,239	11/03/2003	Andrew S. Pekosz	60005161-0114	3764

26263 7590 08/11/2005

SONNENSCHEIN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

EXAMINER	
SALVOZA, M FRANCO G	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,239	PEKOSZ ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/24/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) *26-94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 03/17/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Salvoza.

2. In correspondence dating February 25, 2005, applicant elected Group I, claims 1-19 and 21-25. Applicant requested that amended claim 20 be added to Group I. Applicant also requests that the restriction be withdrawn because of the claim that a search and examination of the entire application can be made without serious burden.

Applicant's arguments are considered but are found unpersuasive. The separate groups may share common features within the class but have different method steps and different effects such as detecting the presence of a negative strand virus, determining a differential diagnosis, detecting different segmented RNA viruses and screening for targets. They are patentably distinct inventions, and the restriction requirement is maintained for reasons of record.

3. Claims 1-25 are pending and under consideration.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it lacks proper signatures. Examiner notes the refiling of a revised declaration/power of attorney on November 13, 2003 to designate a proper order of inventors. Please refile a properly signed and dated executed oath/declaration.

Examiner also notes the entry of the change in the power of attorney.

Specification

Application number is missing from the first page. Please correct.

Application number is missing from the abstract. Please correct.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). In the instant case, there are two claims numbered 76. Misnumbered claim 76 been renumbered 77, and each claim thereafter until 87 (now 88) has been renumbered.

In addition, claim 21 refers to a transcription termination signal, but claim 11 only refers to a transcription termination site. It is not clear whether these are equivalent. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites the limitation "wherein the transcription termination signal is a transcription termination signal for RNA polymerase I." There is insufficient antecedent basis for this limitation in the claim, since claim 11 contains no reference at all to a transcription termination signal, rather it claims a transcription termination site.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-16, 19-23, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent # 6, 270, 958 by Olivo et al. This patent, which teaches the detection of negative strand RNA viruses, is proper under 102(b) since it was issued on August 7, 2001, which is more than one year prior to applicant's date of application, November 3, 2003.

Claim 10 teaches a method for detecting the presence, absence or quantity of a segmented negative strand virus in a biological specimen suspected of comprising the segmented negative strand virus, the method comprising contacting the biological specimen with a genetically engineered vertebrate cell comprising a recombinant DNA molecule that comprises a reporter gene encoding a polypeptide. In column 16, Claim 11 of the Olivo et al. patent teaches a method for detecting a negative-strand RNA virus, the method comprising providing a genetically

engineered cell which comprises a cDNA comprising a minigenome and miniantigenome of the negative strand RNA virus, wherein the miniantigenome comprises a nucleotide sequence encoding a reporter gene, wherein expression of the reporter gene product is dependent upon the presence of the negative-strand RNA virus.

Claim 11 is drawn to a recombinant DNA molecule that comprises a promoter for a DNA-dependent RNA polymerase, a transcription initiation site for the DNA-dependent RNA polymerase, a DNA sequence encoding an artificial segment and a transcription termination site. Claim 12 recites a promoter for a DNA-dependent RNA polymerase that is a promoter for RNA polymerase I, and claim 13 teaches the method where the transcription initiation site is a transcription initiation site for RNA polymerase I. In claim 14, the application recites that the "transcript of the artificial segment is in an anti-sense orientation."

The Olivo et. al. patent teaches in column 3, line 42, that "a minigenome RNA is synthesized which contains an untranslatable negative-sense copy of the reporter gene ORF." The Olivo et al. patent also teaches in column 3, line 60 that infection of the cell with the negative strand virus introduces all the gene products necessary to produce from the DNA translatable mRNA molecules, which indicates the use of RNA polymerase I anticipating claims 12 and 13.

Applicant's claim 15 recites that the artificial segment is operably linked to the promoter such that "a transcript of the artificial segment is in a sense orientation." In column 3, line 45, the Olivo et al. patent teaches a miniantigenome that contains a positive sense copy of the reporter gene ORF. Furthermore, claim 16 recites a segment comprising a cDNA of a 5'UTR segment of a negative strand RNA virus, the reporter gene, and a cDNA of a 3' UTR of a segment of a

negative strand RNA virus, wherein at least one of the 3' UTR and the 5' UTR is a UTR of the virus suspected of comprising the biological sample. Olivo et al. anticipates claim 16 because the patent teaches in column 6, line 66 that the nucleic acid molecule is intended to be integrated into the cell nucleus, which would inherently include the presence of these 5' and 3' untranslated regions in order to do so.

In claims 19 and 20, the application recites a polypeptide or polypeptides selected from the group consisting of chloroamphenicol acetyl transferase, ß-galactosidase, ß-glucorinidase, renilla luciferase, firefly luciferase, a green fluorescent protein, and secreted alkaline phosphatase. However, the patent teaches peptides in claim 8 wherein "the reporter gene product is ß-galactosidase, chloramphenicol acetyl transferase, luciferase, alkaline phosphatase, green fluorescent protein or ß-glucuronidase." Olivo et al. also teaches the use of transcription termination signals for expression of the viral nucleic acids in column 9, line 33 that would anticipate the signals for RNA polymerase I, as the patent anticipated for claims 12 and 13.

Applicant's claim 22 recites that a "transcription termination site comprises a sequence encoding a self-cleaving ribozyme." The Olivo et al. patent teaches in column 8, line 35 a cDNA that "also comprises a self-cleaving ribozyme located between the transcription terminator and 3' terminus of the minigenome or miniantigenome."

Claim 23 is drawn to a "genetically engineered vertebrate cell is a stably transfected genetically engineered vertebrate cell." This claim is also anticipated by the Olivo et al. patent in column 6, line 22, as the patent teaches a "stably transformed cell" under its description of preferred embodiments.

Finally, claim 25 is drawn to a host of transfected cells including a BHK cell, a Chinese

hamster ovary cell, and a monkey primary kidney cell. In column 6, line 46, the patent teaches that "susceptible cells for negative-strand RNA viruses included, but are not limited to baby hamster kidney cells, African green monkey cells... and the like." Applicant's other examples of transfected cells includes cells that are well known candidates in the art, and claim 25 is therefore anticipated under 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6, 7, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,270,958 to Olivo et. al. It would be prima facie obvious to one of ordinary skill in the art when using either RNA or DNA as a construct.

Claims 2, 17, 18, 24 are also rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,270,958 to Olivo et. al. and Neumann et al. One of ordinary skill in the art would have been motivated to detect various types of influenza using the assay of Olivo et. al. in a sample. One would have a reasonable expectation of success of detecting influenza A, B, or C using the assay of Olivo et al. since the assay detects any negative strand virus. In addition, Neumann et al. and Olivo et al. use polymerase I mediated expression of viral nucleic acids.

Claims 4, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,270,958 to Olivo et. al. and Fodor et al. One of ordinary skill in the art would have been

motivated to use the nucleoprotein or NP segment because Fodor et al. teaches that the nucleoprotein is able to encapsidate, replicate, transcribe and function in human cells used in the assay of Olivo et al. The segments can function in the reporter gene assays and have a reasonable expectation of success based on Olivo et al., which teaches the reporter gene assay.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza
Patent Examiner

8/8/05

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600